Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparing the therapeutic effects of curcumin mediated photodynamic therapy and topical corticosteroid in tratment of erosive OLP

Protocol summary

Study aim
The effect of curcumin mediated photodynamic therapy on healing of oral lichen planus

Design
A triple blind randomized controlled clinical trial,split mouth design. 7 patients with bilaterally erosive OLP enrolled and followed

Settings and conduct
This clinical trial will be conducted in 1401 in the Department of Oral and Maxillofacial Diseases of Shiraz Dental Faculty. 7. Patients with bilateral lesions of lichen planus are included in the study. There are 2 groups of lesions: lesions treated with triamcinolone mouthwash and placebo photodynamic therapy as control lesions, and lesions treated with triamcinolone mouthwash and curcumin-mediated photodynamic therapy. Each patient will receive placebo and photodynamic therapy in three sessions in one week. Patients are initially evaluated and followed up with follow-up sessions. Since all patients received triamcinolone acetonide for two weeks, the possible difference in results can be attributed to the therapeutic effect of curcumin-mediated photodynamic therapy.

Participants/Inclusion and exclusion criteria
Inclusion criteria:. Symptomatic erosive lesions Exclusion criteria: Age < 18 years systemic diseases, lichenoid reactions

Intervention groups
14 sides with oral lichen planus are randomly divided into intervention and control sides by block randomization method. Since we do not intend to exclude any patient from standard OLP treatment, all groups will receive triamcinolone acetonide and nystatin mouthwash for two weeks, and will be tapered according to the standard protocol. Intervention lesions will receive three sessions of photodynamic therapy in one week, and control lesions will receive placebo gel and photodynamic therapy (placebo gel and off light source).

Main outcome variables
Thongprasom index, REU clinical score; VAS

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20221016056202N1**
Registration date: **2022-10-23, 1401/08/01**
Registration timing: **prospective**

Last update: **2022-10-23, 1401/08/01**
Update count: **0**

Registration date
2022-10-23, 1401/08/01

Registrant information

Name
hanieh farahmand

Name of organization / entity

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-11-06, 1401/08/15

Expected recruitment end date
2023-02-04, 1401/11/15

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date

empty

Scientific title
Comparing the therapeutic effects of curcumin mediated photodynamic therapy and topical corticosteroid in tratment of erosive OLP

Public title
Comparing curcumin mediated photodynamic therapy and topical corticosteroid in tratment of oral OLP

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Clinical diagnosis of OLP by 2 oral medicine specialists Presence of bilateral errosive symptomatic lesions Patients willing to actively participate in the study Patients that are capable of performing the exact instructions of the treatment protocol.

Exclusion criteria:
Age < 18 years Pregnancy or lactation Uncontrolled systemic diseases (hepatopathies, coagulopathies,auto immune or haematological diseases) History of allergic reactions to the active ingredient (curcumin) used in the clinical trial Presence of histological signs of dysplasia in the biopsy specimen Evidence of lichenoid lesions due to specific causes (dental materials, use of drugs inducing lichenoid reactions such as hypertensive or diabetic medications, etc.) Smokers or heavy drinkers of alcohol. Diabetic patients Patients with photosensivity Lichenoid reaction

Age
From **18 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **14**
More than 1 sample in each individual
Number of samples in each individual: **2**
7 patient with bilateral symptomatic erosive lesions. a total of 14 lesions, 7 case lesions and 7 control lesions.

Randomization (investigator's opinion)
Randomized

Randomization description
Each patient with bilateral erosive OLP included in the study will be considered as follows: one side of the lesion will be the case and the other side will be the control lesion. . The experimental and control side of each patient is randomly selected using randomized blocks. Each block was considered with 4 allocations, including 2 allocations for the intervention and 2 allocations for the control group. Six possible sequences of treatment allocation are listed in each block, each written on a card. Each time a block was selected and the treatment sequence was recorded until treatment allocation was completed for all 7 participants. Randomization will be done by the methodologist. Allocation concealment will be performed by the principal investigator. A sequence is written on each of the 14 cards and sealed. Pockets are placed in a box. An envelope will be assigned to each participant based on the order of registration.

Blinding (investigator's opinion)
Triple blinded

Blinding description
The main researcher, who is responsible for examining and evaluating the lesions before and after the intervention, is unaware of which of the bilateral lesions of the patients is the case or the control. Another researcher is responsible for conducting the therapeutic intervention. The patients do not know which lesions are in the case or control group. The statistician who performs the data analysis is unaware of the case group and control.As a result, the study will be triple blind.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Research Ethics Committees of School of Dentistry-Shiraz University of Medical Sciences

Street address
Zand Street, Namazi Square, Shiraz University of Medical Sciences

City
shiraz

Province
Fars

Postal code
71956-15878

Approval date
2022-08-31, 1401/06/09

Ethics committee reference number
IR.SUMS.DENTAL.REC.1401.067

Health conditions studied

1

Description of health condition studied
oral lichen planus

ICD-10 code
L43

ICD-10 code description
Lichen planus

Primary outcomes

1

Description
pain
Timepoint
days 0 and 7 and 14 and 28 and 56
Method of measurement
visual analogue scale

2

Description
size of lesion
Timepoint
days 0 and 7 and 14 and 28 and 56
Method of measurement
Digital caliper

3

Description
Clinical manifestations of inflammation
Timepoint
days 0 and 7 and 14 and 28 and 56
Method of measurement
Thongprasom sign scoring

4

Description
Clinical Efficacy of treatment
Timepoint
days 0 and 7 and 14 and 28 and 56
Method of measurement
REU

Secondary outcomes

1

Description
Allergy to curcumin
Timepoint
days 1 and 3 and 5
Method of measurement
Observe the side effects of increased sensitivity

Intervention groups

1

Description
Intervention group: In each photodynamic therapy session Sinanomin 1%(Topical gel contains %1 curcumin as nanoliposome from Exir Nanosina company will applied for 10 minutes in the side that is randomly selected as the case. After that a light cure device will be applied for irradiation with a blue light emitting wavelength of 470 nm for 5 min.
Category
Treatment - Drugs

2

Description
Control group: The other side of each patient that is considered as the control side with receive a placebo irradiation for 5 minutes with no light.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Faculty of Dentistry, Shiraz University of Medical Sciences
Full name of responsible person
Hanieh Farahmand
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Shiraz, Qasrdasht St., corner of Mehr St., Shiraz Faculty of Dentistry
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No

Title of funding source
Research Vice President of Shiraz University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
Shiraz University of Medical Sciences
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
I have decided to publish the article in domestic or foreign magazines. Complete information will be accessible in this way
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available